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\*Admitted only in Maryland  
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•Practice Limited to  
Federal Agencies

November 10, 2004

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

### Mail Stop Amendment

Re: U.S. Utility Patent Application  
Application No. 10/764,604; Filed: January 27, 2004  
For: Compositions and Methods for Treating  
Cancer Using IGSF9 and LIV-1  
Inventors: McLachlan *et al.*  
Our Ref: 2159.0030001/LBB/PAC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Twenty-six pages of Form PTO-1449;
3. Copies of documents AL1-AN1, AR1-AT1, AR2-AT2, AR3-AT3, AR4-AT4, AR5-AT5, AR6-AT6, AR7-AT7, AR8-AT8, AR9-AT9, AR10-AT10, AR11-AT11, AR12-AT12, AR13-AT13, AR14-AT14, AR15-AT15, AR16-AT16, AR17-AT17, AR18-AT18, AR19-AT19, AR20-AT20, AR21-AT21, AR22-AT22, AR23-AT23, AR24-AT24, AR25-AT25 and AR26-AT26 as listed on Form PTO-1449; and
4. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
November 10, 2004  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky  
Attorney for Applicants  
Registration No. 35,086

LBB/PAC:dbj  
Enclosures

331431\_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MC LACHLAN *et al.*

Appl. No.: 10/764,604

Filed: January 27, 2004

For: **Compositions and Methods for  
Treating Cancer Using IGSF9  
and LIV-1**

Confirmation No. 6570

Art Unit: 1614

Examiner *To Be Assigned*

Atty. Docket: 2159.0030001/LBB/PAC

**Information Disclosure Statement Under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of U.S. patents and patent application publications, AA1-AK1, AA2-AK2, AA3-AK3, and AA4-AD4, cited on the attached Form PTO-1449 are not submitted in accordance with 1276 OG 55 because this application was filed after June 30, 2003. Copies of documents AL1-AN1, AR1-AT1, AR2-AT2, AR3-AT3, AR4-AT4, AR5-AT5, AR6-AT6, AR7-AT7, AR8-AT8, AR9-AT9, AR10-AT10, AR11-AT11, AR12-AT12, AR13-AT13, AR14-AT14, AR15-AT15, AR16-AT16, AR17-AT17, AR18-AT18, AR19-AT19, AR20-AT20, AR21-AT21, AR22-AT22, AR23-AT23, AR24-AT24, AR25-AT25 and AR26-AT26 are provided.

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on

information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Attorney for Applicants  
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Date: Nov 10, 2004  
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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
2159.0030001/LBB/PACAPPLICATION NO.  
10/764,604FIRST NAMED INVENTOR  
McLachlan, et al.FILING DATE  
January 27, 2004ART UNIT  
1614**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA1	4,676,980	06/30/1987	Segal et al.			09/23/1985
AB1	4,722,848	02/02/1988	Paoletti et al.			06/19/1984
AC1	4,816,567	03/28/1989	Cabilly et al.			04/08/1983
AD1	4,831,175	05/16/1989	Gansow et al.			09/05/1986
AE1	4,946,778	08/07/1990	Ladner et al.			01/19/1989
AF1	5,099,069	03/24/1992	Gansow et al.			12/16/1988
AG1	5,124,471	06/23/1992	Gansow et al.			03/26/1990
AH1	5,229,275	07/20/1993	Goroff			04/26/1990
AI1	5,246,692	09/21/1993	Gansow et al.			08/22/1991
AJ1	5,286,850	02/15/1994	Gansow et al.			05/11/1992
AK1	5,434,287	07/18/1995	Gansow et al.			11/04/1993

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL1	WO 93/11161	06/10/1993	WIPO			N/A
AM1	WO 94/13804	06/23/1994	WIPO			N/A
AN1	EP 0 368 684 B1	03/09/1994	Europe			N/A
AO				/		
AP						

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	1	Bierer, B. E., et al., "Synergistic T Cell Activation Via The Physiological Ligands For CD2 And The T Cell Receptor," <i>J. Exp. Med.</i> 168: 1145-1156, Rockefeller University Press (1988)
AS	1	Bird, R. E., et al., "Single-Chain Antigen-Binding Proteins," <i>Science</i> 242:423-426, American Association for the Advancement of Science (1988)
AT	1	Bowie, J. U., et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> 247:1306-1310, American Association for the Advancement of Science (1990)

EXAMINER

DATE CONSIDERED

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 2159.0030001/LBB/PAC	APPLICATION NO. 10/764,604
		FIRST NAMED INVENTOR McLachlan, et al.	
		FILING DATE January 27, 2004	ART UNIT 1614

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,460,785	10/24/1995	Rhodes et al.			01/03/1992
	AB2	5,545,806	08/13/1996	Lonberg et al.			12/16/1992
	AC2	5,545,807	08/13/1996	Surani et al.			08/05/1994
	AD2	5,567,610	10/22/1996	Borrebaeck et al.			10/17/1994
	AE2	5,569,825	10/29/1996	Lonberg et al.			12/17/1991
	AF2	5,585,089	12/17/1996	Queen et al.			06/07/1995
	AG2	5,591,669	01/07/1997	Krimpenfort et al.			05/30/1995
	AH2	5,648,267	07/15/1997	Reff			11/03/1993
	AI2	5,658,570	08/19/1997	Newman et al.			01/25/1995
	AJ2	5,693,761	12/02/1997	Queen et al.			06/07/1995
	AK2	5,693,762	12/2/1997	Queen et al.			06/07/1995

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	2	Breathnach, R., et al., "Ovalbumin gene: Evidence for a leader sequence in mRNA and DNA sequences at the exon-intron boundaries," <i>Proc. Natl. Acad. Sci. USA</i> 75:4853-4857, National Academy of Sciences (1978)
AS	2	Brennan, M., et al., "Preparation of Bispecific Antibodies by Chemical Recombination of Monoclonal Immunoglobulin G1 Fragments," <i>Science</i> 229:81-83, American Association for the Advancement of Science (1985)
AT	2	Brüggemann, M., et al., "Designer Mice: The Production of Human Antibody Repertoires in Transgenic Animals," in <i>Generation of Antibodies by Cell and Gene Immortalization</i> , Terhorst, C., et al., Karger AG, Basel, Switzerland, pp.33-40 (1993)

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**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	5,693,780	12/2/1997	Newman et al.			06/07/1995
	AB3	5,733,779	03/31/1998	Reff			06/07/1995
	AC3	5,736,137	04/07/1998	Anderson et al.			11/03/1993
	AD3	5,756,096	05/26/1998	Newman et al.			06/07/1995
	AE3	5,811,524	09/22/1998	Brams et al.			06/07/1995
	AF3	5,843,439	12/01/1998	Anderson et al.			06/07/1995
	AG3	5,892,019	04/06/1999	Schlom et al.			09/01/1994
	AH3	5,939,598	08/17/1999	Kucherlapati et al.			07/30/1992
	AI3	5,969,108	10/19/1999	McCafferty et al.			01/08/1993
	AJ3	6,017,733	01/25/2000	Reff			01/26/1998
	AK3	6,075,181	06/13/2000	Kucherlapati et al.			06/07/1995

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	3	Carrasquillo, J. A., et al., "Improved Imaging of Metastatic Melanoma with High Dose 9.2.27 In-111 Monoclonal Antibody," <i>J. of Nucl. Med.</i> 26:P67, Society of Nuclear Medicine, Inc. (1985).
AS	3	Carter, P., et al., "Humanization of an anti-p185 <sup>HER2</sup> antibody for human cancer therapy," <i>Proc. Natl. Acad. Sci. USA</i> 89: 4285-4289, National Academy of Sciences (1992)
AT	3	Chabner, et al., "Antineoplastic Agents," in <i>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</i> , 9 <sup>th</sup> ed., Wonsiewicz, M. J., and McCurdy, P., eds., McGraw-Hill, New York, NY, pp. 1233-1287 (1996).

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		FIRST NAMED INVENTOR McLachlan, <i>et al.</i>	
		FILING DATE January 27, 2004	ART UNIT 1614

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	6,159,730	12/12/2000	Reff			03/30/1999
	AB4	6,193,980	02/27/2001	Efstathiou <i>et al.</i>			09/17/1997
	AC4	6,399,061	06/04/2002	Anderson <i>et al.</i>			06/07/1995
	AD4	6,682,734	01/27/2004	Anderson <i>et al.</i>			06/07/1995
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	4	Chothia, C., and Lesk, A. M., "Canonical Structures for the Hypervariable Regions of Immunoglobulins," <i>J. Mol. Biol.</i> 196:901-917, Academic Press Ltd. (1987)
AS	4	Clackson, T., <i>et al.</i> , "Making antibody fragments using phage display libraries," <i>Nature</i> 352:624-628, Macmillan Magazines Ltd. (1991)
AT	4	Cunningham, B. C., and Wells, J. A., "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis," <i>Science</i> 244:1081-1085, American Association for the Advancement of Science (1989)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>5</u>	De Vos, A. M., et al., "Human Growth and Extracellular Domain of Its Receptor: Crystal Structure of the Complex," <i>Science</i> 255:306-312, American Association for the Advancement of Science (1992)
	AS	<u>5</u>	Doudney, K., et al., "Cloning and Characterization of <i>Igsf9</i> in Mouse and Human: A New Member of the Immunoglobulin Superfamily Expressed in the Developing Nervous System," <i>Genomics</i> 79:663-670, Elsevier Science (May 2002)
	AT	<u>5</u>	Fields, S., and Song, O., "A novel genetic system to detect protein-protein interactions," <i>Nature</i> 340: 245-246, Macmillan Magazines Ltd. (1989)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>6</u>	Freedman, A. S., and Nadler, L. M., "Malignant Lymphomas," in <i>Harrison's Principles of Internal Medicine</i> , 13 <sup>th</sup> ed., Isselbacher, K. J., <i>et al.</i> , eds., McGraw Hill, Inc., New York, NY (1994)
	AS	<u>6</u>	Freshney, R. I., "Quantitation and Experimental Design," in <i>Culture of Animal Cells</i> , Alan R. Liss, Inc., New York, NY, pp. 227-296 (1987)
	AT	<u>6</u>	Gautier, C., <i>et al.</i> , " $\alpha$ -DNA IV: $\alpha$ -anomeric and $\beta$ -anomeric tetrathymidylates covalently linked to intercalating oxazoloypyridocarbazole. Synthesis, physicochemical properties and poly (rA) binding," <i>Nucleic Acids Research</i> 15:6625-6641, IRL Press Ltd. (1987)

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## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>7</u>	Gentz, R., et al., "Bioassay for trans-activation using purified human immunodeficiency virus tat-encoded protein: Trans-activation requires mRNA synthesis," <i>Proc. Natl. Acad. Sci. USA</i> 86: 821-824, National Academy of Sciences (1989)
	AS	<u>7</u>	Giovanella, B. C., et al., "Heterotransplantation of Human Malignant Tumors in "Nude" Thymusless Mice. II. Malignant Tumors Induced by Injection of Cell Cultures Derived From Human Solid Tumors," <i>Journal of the National Cancer Institute</i> 52:921-930, U.S. Dept. of Health, Education, and Welfare (1974)
	AT	<u>7</u>	Goding, J. W., "Production of Monoclonal Antibodies," in <i>Monoclonal Antibodies: Principles and Practice</i> , 2 <sup>nd</sup> ed., Academic Press Inc. , London, pp. 59-103 (1986).
EXAMINER		DATE CONSIDERED	

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## **U.S. PATENT DOCUMENTS**

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>8</u>	Griffiths, A. D., et al., "Human anti-self antibodies with high specificity from phage display libraries," <i>EMBO J.</i> 12:725-734, Oxford University Press (1993).
	AS	<u>8</u>	Holliger, P., et al., "'Diabodies': Small bivalent and bispecific antibody fragments," <i>Proc. Natl. Acad. Sci. USA</i> 90:6444-6448, National Academy of Sciences (1993)
	AT	<u>8</u>	Huse, W. D., et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," <i>Science</i> 246:1275-1281, American Association for the Advancement of Science (1989)

Page 1

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FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 2159.0030001/LBB/PAC  FIRST NAMED INVENTOR McLachlan, et al.	APPLICATION NO. 10/764,604
	FILING DATE January 27, 2004	ART UNIT 1614

## **FOREIGN PATENT DOCUMENTS**

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>9</u>	Huston, J. S., et al., "Protein engineering of antibody binding sites: Recovery of specific activity in an anti-digoxin single-chain Fv analogue produced in <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 85:5879-5883, National Academy of Sciences (1988)
	AS	<u>9</u>	Inoue, H., et al., "Sequence-dependent hydrolysis of RNA using modified oligonucleotide splints and RNase H," <i>Fefs Letters</i> 215:327-330, Elsevier Science Publishers B.V. (1987)
	AT	<u>9</u>	Inoue, H., et al., "Synthesis and hybridization studies on two complementary nona(2'-O-methyl)ribonucleotides," <i>Nucleic Acids Research</i> 15:6131-6148, IRL Press Ltd. (1987)
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Page 10 of 26		
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## **U.S. PATENT DOCUMENTS**

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>10</u>	Jakobovits, A., et al., "Analysis of homozygous mutant chimeric mice: Deletion of the immunoglobulin heavy-chain joining region blocks B-cell development and antibody production," <i>Proc. Natl. Acad. Sci. USA</i> 90:2551-2555, National Academy of Sciences (1993)
	AS	<u>10</u>	Jakobovits, A., et al., "Germ-line transmission and expression of a human-derived yeast artificial chromosome," <i>Nature</i> 362:255-258, Macmillan Magazines Ltd. (1993)
	AT	<u>10</u>	Johnson, K. S., and Chiswell, D.J., "Human antibody engineering," <i>Curr. Opin. Struct. Biol.</i> 3:564-571, Current Biology Ltd. (1993)

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## **U.S. PATENT DOCUMENTS**

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